PATENT COOPERATION TREATY

DOT

From the INTERNATIONAL SEARCHING AUTHORITY	PCT
To: CARPMAELS & RANSFORD Attn. Tunstall, C.S. 43-45 Bloomsbury Square London WcLl 2RA UNITED KINGDOM 02 JUN 2005 CARPMAELS & RANSFOR	NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WITETRA OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION (PCT Rule 44.1)
Methodaen	Date of mailing (day/month/year) 02/06/2006
Applicant's or agent's file reference P040401WO	FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/GB2006/001030	International filing date (day/month/year) 21/03/2006
Applicant CILAG AG INTERNATIONAL	
1. X The applicant is hereby notified that the international search Authorith have been established and are transmitted herewith Filling of amendments and statement under Article 19: The applicant is entitled, if he so wishes, to amend the claim When? The time limit for filling such amendments is nor international Search Report. Where? Directly to the International Bursau of WIPO, 34 1211 Geneva 20, Switzerland, Fascinine Not. (2) 1211 Geneva 20, Switzerland, Fascinine Not. (2) 1211 Geneva 20, Switzerland, Fascinine Not. (2) 121 Geneva 20, Switzerland, Fascinine Not. (2) 131 General barriers of the international search Article 17(2)(a) to that effect and the written opinion. (1 the international search applicant is request to forward the texts of both the protein or decision has been made yet on the protest; ne applicant for equal to the protein or the protein o	th. """ "" "" "" "" "" "" "" ""

Name and mailing address of the International Searching Authority

ML-2280 HV Rijswijk NL-2280 HV Rijswijk Tel, (-31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016

Authorized officer

Elisabeth Reinecke

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the fiting of amendments under article 15. The Notes are based on the requirements of the Patient Cooperation Treaty, the Regulations and the Administrative instructions under that Treaty, in case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WHZO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having roceived the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims,description and drawings) may be amended during the international periminary examination procedure, there is usually no need to the samentiments of the claims under Article 19 international periminary examination in the claim surface and the claims are considered and the claims are claims are considered and the claims are claims are considered and the claims are considered and the claims are claims are considered and the claims are considered and the claims are considered and the claims are claims are considered and the claims are claims are considered and the claim

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no International search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 296).

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time finit expires label. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the international Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Pulle 46.1).

Where not to file the amendments?

The amendments may only be flied with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Section 2056b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER		see Form PCT/ISA/220
P040401WO	ACTION	as well	as, where applicable, item 5 below.
International application No.	International filing date (day/mont	h/year)	(Earliest) Priority Date (day/month/year)
	01/02/0000		06/04/2005
PCT/GB2006/001030	21/03/2006		06/04/2005
Applicant			
CILAG AG INTERNATIONAL			
This international search report has been according to Article 18. A copy is being tra	prepared by this International Seam ansmitted to the International Burea	hing Autho	ority and is transmitted to the applicant
This international search report consists of	of a total of 7 she	ets.	
· '	a copy of each prior art document		report.
,			
Basis of the report			
a. With regard to the language, the			
_ =	application in the language in which	it was filed	
	e international application into mished for the purposes of internati	onal searc	, which is the language h (Rules 12.3(a) and 23.1(b))
b. With regard to any nucley	otide and/or amino acid sequence	disclosed	in the international application, see Box No. I.
2. X Certain claims were fou	nd unsearchable (See Box No. II)		
3. Unity of invention is lac	king (see Box No III)		
With regard to the title, The text is approved as su	- without his the applicant		
I 🖃 "	shed by this Authority to read as follo		
the text has been establis	sted by this Authority to read as folio	ows.	
1			
With regard to the abstract,			
the text is approved as su			
			ity as it appears in Box No. IV. The applicant rch report, submit comments to this Authority
With regard to the drawings,			
a. the figure of the drawings to be	published with the abstract is Figure	No1	
X as suggested by	the applicant		
as selected by th	is Authority, because the applicant	ailed to su	ggest a figure
	is Authority, because this figure bet	ter charact	erizes the invention
b. none of the figures is to b	e published with the abstract		
L			

International application No.

PCT/GB2006/001030

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

An injection device (110) comprises a housing (112) adapted to receive a syrringe (122) having a discharge nozzle (118), an actuator (114) and a drive (120) acted upon by the actuator which acts upon the syringe to advance it from a retracted position in which the discharge nozzle is contained within the housing to an extended position in which the discharge nozzle extends from the housing. There is a locking mechanism (116) in communication with the actuator and activatable to be moved from a locked position in which the actuator is prevented from releasing the drive to an unlocked position in which the actuator is operable to act upon the drive to advance the syringe. The locking mechanism or the housing includes integrally formed biasing means (210) adapted to return the locking mechanism to a locked position when it is not activated. There is no need for separate springs to be used to bias the releasable locking mechanism out of the housing.

International application No PCT/GB2006/001030

A. CLASSIFICATION OF SUBJECT MATTER INV. A61M5/20

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Х	US 4 194 505 A (SCHMITZ, WILLIAM L) 25 March 1980 (1980-03-25)	1,2
	column 3, line 49 - column 4, line 12; figures 2.3.8	
Υ	figure 3	3-7
Y	US 4 378 015 A (WARDLAW ET AL) 29 March 1983 (1983-03-29) abstract; figures 1,4	1-7
Y	US 2003/105430 A1 (LAVI GILAD ET AL) 5 June 2003 (2003-06-05) column 10, paragraphs 165,166; figures 49-55	1-7
A	US 6 575 939 B1 (BRUNEL MARC) 10 June 2003 (2003-06-10) abstract; figures	1
	-/	

X Further documents are listed in the continuation of Box C.	X See patent family annex.
 Special categories of client documents: A document defining the general state of the art which is not considered to be of particular relevance enter decrement but published on or after the international stag date. the grade of the international stag date of the international stag date. which is the horsy threw dealers on priority, date of another citation or other special reason, is a specialism of such as the publication date of another citation or other special reason, is a specialism. document referring to an oral disclosure, use, exhibition or other mean: p* document published prior to the international filling date but alort than the provisy date citation. 	**T* later document published after the international filing date or priority date aim not in conflict with the application but or priority date aim not in conflict with the application but invention. **Z* Occurrent of particular relevance, the claimod invention cannot be considered noted or clamb de considered to exceed the considered noted or clamb de considered to involve stip when the document is taken above the considered noted to exceed the considered noted to exceed the considered noted the considered noted to exceed the considered noted to exceed the considered noted that the considered noted that the considered noted that the considered noted that the considered with one or more other such documents occurred to combinate one public publicies on a present skilled in the art. **X* document member of the same patient family
Date of the actual completion of the international search 23 May 2006	Date of mailing of the international search report 02/06/2006
Name and mailing address of the ISM European Patent (Dfice, P.B. 5818 Patentlaan 2 NL - 2200 IV Rijswijk Tel. (+31-70) 340-2400, Tx. 31 651 epo nil, Fax: (+31-70) 340-3016	Authorized officer Ehrsam, F

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International application No PCT/GB2006/001030

C(Continua	ation). DOCUMENTS CONSIDERED TO BE RELEVANT	
ategory*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	US 5 176 643 A (KRAMER ET AL) 5 January 1993 (1993-01-05) abstract; figures	1–7
•	US 5 540 709 A (RAMEL ET AL) 30 July 1996 (1996-07-30) abstract; figures 7,8	1-7

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 8

Claim 8 is lacking clarity since it relates to the drawings and therefore no meaningful search could be executed

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCI). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be

International application No. PCT/GB2006/001030

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)
This international Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:
Claims Nos.: Claims Nos.: Claims Nos.: S Claims Nos.: B Claims Nos.: S Claims Nos.: Claims Nos.: S Claims Nos.: Claims Nos.: Claims Nos.: Claims Nos.: S Claims Nos.: Cla
Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).
Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)
This international Searching Authority found multiple inventions in this international application, as follows:
As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
Remark on Protest The additional search fees were accompanied by the applicant's protest. No protest accompanied the payment of additional search fees.

Information on patent family members

International application No PCT/GB2006/001030

Patent do cited in sea			Publication date		Patent family member(s)	Publication date
US 4194	505	A	25-03-1980	NONE		•
US 4378	8015	Α	29-03-1983	NONE		
US 2003	3105430	A1	05-06-2003	NONE		
US 6575	939	B1	10-06-2003	AT	227593 T	15-11-2002
				AU	1767999 A	23-08-1999
				DE	69809471 D	1 19-12-2002
				DE	69809471 Ta	2 02-10-2003
				EP	1053037 A	1 22-11-2000
				ES	2188036 T	3 16-06-2003
				FR	2774294 A	1 06-08-1999
				WO	9939759 A	1 12-08-1999
US 5176	643	Α	05-01-1993	AU	659374 B	2 11-05-1995
				AU	1912492 A	21-12-1992
				AU	2843095 A	12-10-1995
				CA	2109106 A	1 12-11-1992
				EP	0582651 A	
				JP	6508773 T	06-10-1994
				WO	9219296 A	2 12-11-1992
US 5540	709	Α	30-07-1996	NONE		

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY PCTWRITTEN OPINION OF THE see form PCT/ISA/220 INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1) Date of mailing (dav/month/year) see form PCT/ISA/210 (second sheet) Applicant's or agent's file reference FOR FURTHER ACTION see form PCT/ISA/220 See paragraph 2 below International application No. International filing date (day/month/year) Priority date (day/month/year) PCT/GB2006/001030 21.03.2006 06.04.2005 International Patent Classification (IPC) or both national classification and IPC INV. A61M5/20 Applicant CILAG AG INTERNATIONAL This opinion contains indications relating to the following items: Box No. I Basis of the opinion □ Box No. II Priority Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability ☐ Box No. IV Lack of unity of invention Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement ☐ Box No. VI Certain documents cited Box No. VII Certain defects in the international application Box No. VIII Certain observations on the international application FURTHER ACTION If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered. If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later. For further options, see Form PCT/ISA/220. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:

European Patent Office D-80298 Munich

Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 Date of completion of this opinion

see form PCT/ISA/210 Authorized Officer

Ehrsam, F

Telephone No. +49 89 2399-2343



WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

2.

International application No. PCT/GB2006/001030

_		· · · · · · · · · · · · · · · · · · ·				
_	Box	No. I Basis of the opinion				
1.	. With regard to the language, this opinion has been established on the basis of:					
	1	the international application in the language in which it was filed				
		a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).				
2.	With nece	regard to any nucleotide and/or amino acid sequence disclosed in the international application and ssary to the claimed invention, this opinion has been established on the basis of:				
	a. typ	pe of material:				
		a sequence listing				
		table(s) related to the sequence listing				
	b. fo	rmat of material:				
		on paper				
		in electronic form				
	c. tin	ne of filing/furnishing:				
		contained in the international application as filed.				
		filed together with the international application in electronic form.				
		furnished subsequently to this Authority for the purposes of search.				
3.		In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.				
4.	Addi	tional comments:				

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability							
The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of							
	the entire international application						
\boxtimes	claims Nos. 8						
bec	ause:						
	the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search (specify):						
	the description, claims or drawings (indicate particular elements below) or said claims Nos. are so unclear that no meaningful opinion could be formed (specify):						
	the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed ($specify$):						
Ø	no international search report has been established for the whole application or for said claims Nos. 8						
	a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:						
	☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.						
	☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.						
	pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b).						
	a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.						
	the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.						
	See Supplemental Box for further details						

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Statement
 Novelty (N)

Yes: Claims 3-7 No: Claims 1,2

Inventive step (IS) Yes: Claims

No: Claims 1-7

Industrial applicability (IA) Yes: Claims 1-7
No: Claims

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item III.

1. No examination is carried out since claim 8 has not been search due to lack of clarity.

Re Item V.

- 1 Reference is made to the following documents:
 - D1: US-A-4 194 505 (SCHMITZ, WILLIAM L) 25 March 1980 (1980-03-25)
 - D2: US-A-4 378 015 (WARDLAW ET AL) 29 March 1983 (1983-03-29)
 - D3: US 2003/105430 A1 (LAVI GILAD ET AL) 5 June 2003 (2003-06-05)
 - D4: US-B1-6 575 939 (BRUNEL MARC) 10 June 2003 (2003-06-10)
 - D5: US-A-5 176 643 (KRAMER ET AL) 5 January 1993 (1993-01-05)
 - D6: US-A-5 540 709 (RAMEL ET AL) 30 July 1996 (1996-07-30)

2 INDEPENDENT CLAIM 1

- 2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1 and 2 is not new in the sense of Article 33(2) PCT. Document D1 discloses an injection device where the locking mechanism or the housing includes integrally formed biasing means to return the locking mechanism to a locked position when it is not activated, see in particular element 88 which is pushed back to the locked position by the spring (96) when no action is made on the element (88).
- 2.2 The present application does not meet the criteria of Article 33(1) PCT, because the subject matter of claim 1 does not involve an inventive step in the sense of Article 33(3)PCT.
- 2.2.1 Document D3, which is considered to represent the most relevant state of the art to the subject matter of claim 1, discloses an injection device.
- 2.2.2 The subject-matter of independent claim 1 differs from the disclosure of D3 in

that the locking mechanism or the housing includes integrally formed biasing means to return the locking mechanism to a locked position when it is not activated.

- 2.2.3 The problem to be solved by the present invention may therefore be regarded as improve the security during use.
- 2.2.4 In view of D2 the solution proposed in claim 1 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) since its was obvious for the person skilled in the art to provide flexible arms integrally formed on the locking mechanism to replace the locking mechanism when not used.
- 2.2.5 Therefore the features disclosed in D3 and D2 would be combined by the skilled person, without exercise of any inventive skills in order to solve the problem posed. The proposed solution in independent claim 1 thus cannot be considered inventive (Article 33(3) PCT).

3 DEPENDENT CLAIMS 2-7

Dependent claims 2-7 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT), see in particular documents D4-D6 the respective figures.

Re Item VII.

- The description should have been brought into conformity with the new claims to be filed; care should be taken during revision, especially of the introductory portion including any statements of problem or advantage, not to add subject-matter which extends beyond the content of the application as originally filed (Art. 34 2) b).
- To meet the requirements of Rules 6 3 b) the independent claim should have been properly cast in a two part form, with those features which in combination are part of

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (SEPARATE SHEET)

International application No. PCT/GB2006/001030

the nearest prior art being placed in the first part.

- To meet the requirements of Rule 5.1 a vi, the cited documents should have been identified in the description and the relevant background art therein is to be indicated.
- The features of the claims should have been provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

Re Item VIII.

Claim 1 lacks clarity since due to the fact that the locking mechanism "or" the housing
includes integrally formed biasing means adapted to return the locking mechanism. It
is noted that only the first option "the locking means includes integrally formed
biasing means" is shown in the different figures.